

FDB sees huge value of SPL on patient safety. Timely information is very key to safety.

Tom is a pharmacist. Has long personal history of using product information.

FDB Main business: content provider.

FDB Core drug data = drug information & pricing info;

NDDF+: National Drug Data file, plus = clinical module (xchecking AEs, etc.)

Users/customers of FDB information very variable: e-prescribing, pharmacists, claims adjudication, formulary mgmt, pricing analysis, wholesalers, etc.

FDB employs over 35 clinical pharmacists seek data and make determinations around data and put into format. Many pharmacy techs work on the database and this has worked well because they understand criticality of accuracy. Six sigma methodologies for quality of data, continuous QC approval.

How does FDB obtain information? Information must be timely!

Sources: FDA approved labeling (PIs), associations and contact with about every drug mfg and collect directly from these companies, database acquisition group to supplement information, OTC monographs.

Secondary resources: American Hospital Formulary, Harriet Lane and Briggs for clinical info, review over 300 prof. journals, policy statements, treatment guidelines, etc. Search for triggers to know when information has changed.

Easy to get information on new products. But as things change, it becomes more difficult to get information on a continuing basis. Outdated information can be harmful to the patient, and FDB is acutely attuned to this.

FDB has a formal update policy for updating their modules. Seek daily updates for event based updates, and also looks for information on a cycle.

SPL should improve FDB ability to know when a label change has occurred. SPL is very valuable to the patient in that FDB can now have an opportunity to ensure updates are captured as they happen. FDB was originally paper, then internet, now with SPL – has improved. FDB uses Highlights information in SPL and is very useful.

NCPDP & HL7 SPL Teams trying to coordinate to help downstream SPL users.

Electronic prescribing is growing. Prescription end users must have real time product information. Retail pharmacies and claims payers must have access also to this information. Government is the largest payer of drugs in the world.

Data is provided for **real time** applications.

SPL improvements sought (without undue burdens on mfg):

Codifications of elements of SPL. Eg, codification of indications and auditing electronically. FDB is providing FDA with their requested codifications.

FDC aggregates information at NDC level, as well as other levels. Would like inter-operable information for health records.

Rxnorm is a non proprietary drug concept that describes a product on many levels. May have a use as a common national definition. Coded. Meaningful use requirements 2014? Would like this to become part of SPL.

Pharmacists are primary consumers of NDC level information, prescribers do not interact with NDCs.

SPL is useable as is, but FDB seeks additional improvements. FDB sees SPL as a great asset for public use.

CMS is a payer. FDB's association with CMS. FDB is a customer of CMS. FDB advises CMS and knows what their needs are for drug information, and are able to help to provide them needed information. FDB has very little influence and does not seek influence on CMS policies. FDB is assisting CMS to understand how the information is used by industry.

Potential Issues with Rebates: FDB sometimes uses NCPDP billing units that are in conflict with CMS units for rebate-able product for non-oral doses.

NDC Package Coding on Inner and Outer Packaging – Has become a substantial patient safety issue.

More critical than ever that unit of administration at bedside has barcode or identifier on the physical product that is available on FDB system. Difficult for FDB to gain information about inner packaging NDCs. Mfg does not sell the inner package. FDB needs the inner NDC because electronic barcode has to be in FDB database and quality control is in jeopardy. Fast growing marketplace for electronic information.

Mfg may misunderstand why FDB and other compendia would need that level of information. Mfg may be concerned around confusion of replenishment of stock NDCs or because it is not saleable.

Retail pharmacies and mail order pharmacies often leverage photographic information. Need is for information on commonly and less commonly described.

Photos come from FDB who has about 10,000 images today. Partners allow access to products, FDB takes images under strict requirements. More recently FDB sometimes uses images provided by mfg in some cases.

FDB sometimes takes photos of packaging. Did market research to see what images would be most important. For pills, want to see package. For oral liquid, bottle and liquid in dosage cup (could vary depending upon dispensing).

FDB is excited about NLM Pillbox Initiative. FDB will evaluate if this can be integrated into their image module.

We await Federal Register Notice on Pillbox which is forthcoming.

FDB – does not have images for bordering countries like Canada because it is a very manual process and not feasible currently. May revisit this later if necessary.

*****If discrepancy is seen by mfg in FDB DB, reach out to FDB and identify this to them.*****

Most mfgs have some direct contact with FDB. FDB strives to have a single point of contact at each company to lessen confusion.

Which functional area is usually in touch with FDB?

Many times can be regulatory, marketing, etc. FDB tries to keep a current point of contact. **Critical to mfg that drug information gets to FDB quickly.**

FDB exists because of inaccuracies found in FDA databases and lack of timeliness. FDA is improving, as SPL demonstrates. FDB may use FDA information to audit, but FDB uses mainly quality control measures and is in direct contact with mfg.

What kind of information does FDB want supplied by mfg?

Anytime there is any type of labeling change and FDB can review and update the data. FDB asks mfg for advanced notice when possible.

How successful is FDB at receiving information directly from mfg:

At least 1ce year, FDB sends report and product list and asks mfg to review the list for accuracy and completeness. If mfgs do not respond for long periods of time, then FDB may inactivate the products on their database. This happens only after reaching out to CEO.

There is no external monitoring of FDB information, but intense QA occurs internally. What happens is that FDB data is used in billions of transactions each year, 1500 customers implementing data, 10k HCPs, FDB receives a lot of feedback from customers.

Does FDB transform information? FDB does link information to other sources. FDB does not put out information on drug interaction frequency, but points to other information.

FDB does use physical characteristic information from SPL, but uses their own codified information as most useable. They do not currently use physical dimension information. FDB has found some discrepancies within different sections of SPL and FDB does notify mfg of this information. FDB is still learning and refining how best to use the SPL information.

FDB does not currently use LOINC codes. Considerations underway, but would need to ensure that these codes were being used properly when SPL is developed.

FDB updates data every day, updates within 24 hr.

800 633 3453 – FDB

Identify yourself as mfg and ask for data acquisition specialist to help find out who within the company is the FDB point of contact.